

§ 524.86

524.1132 Hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate otic suspension.
 524.1140 Imidacloprid and ivermectin.
 524.1146 Imidacloprid and moxidectin.
 524.1193 Ivermectin topical solution.
 524.1195 Ivermectin otic suspension.
 524.1200 Kanamycin ophthalmic and topical dosage forms.
 524.1200a Kanamycin ophthalmic ointment.
 524.1200b Kanamycin ophthalmic aqueous solution.
 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.
 524.1240 Levamisole.
 524.1376 2-Mercaptobenzothiazole solution.
 524.1443 Miconazole.
 524.1445 Miconazole, polymyxin B, and prednisolone suspension.
 524.1446 Milbemycin oxime solution.
 524.1450 Moxidectin.
 524.1465 Mupirocin.
 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.
 524.1484b Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.
 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment.
 524.1484d Neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride ear ointment.
 524.1484e Neomycin sulfate and polymyxin B sulfate ophthalmic solution.
 524.1484f Neomycin sulfate, prednisolone acetate, tetracaine hydrochloride eardrops.
 524.1484g Neomycin sulfate-thiabendazole-dexamethasone solution.
 524.1484h Neomycin, penicillin, polymyxin, hydrocortisone suspension.
 524.1484i Neomycin sulfate, hydrocortisone acetate, sterile ointment.
 524.1580 Nitrofurazone ophthalmic and topical dosage forms.
 524.1580a [Reserved]
 524.1580b Nitrofurazone ointment.
 524.1580c Nitrofurazone soluble powder.
 524.1580d [Reserved]
 524.1580e Nitrofurazone ointment with butacaine sulfate.
 524.1600 Nystatin ophthalmic and topical dosage forms.
 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.
 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ophthalmic ointment.
 524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.
 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.
 524.1662a Oxytetracycline hydrochloride and hydrocortisone spray.

21 CFR Ch. I (4–1–12 Edition)

524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.
 524.1742 *N*-(Mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) emulsifiable liquid.
 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.
 524.1881a [Reserved]
 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.
 524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.
 524.1982 Proparacaine hydrochloride ophthalmic solution.
 524.2098 Selamectin.
 524.2101 Selenium disulfide suspension.
 524.2350 Tolnaftate cream.
 524.2482 Triamcinolone spray.
 524.2483 Triamcinolone cream.
 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13873, Mar. 27, 1975, unless otherwise noted.

§ 524.86 Amitraz liquid.

(a) *Specifications*. Amitraz liquid contains 19.9 percent amitraz in an organic solvent.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use*. For dogs for the treatment of generalized demodicosis (*Demodex canis*).

(2) *Amount*. One 10.6 milliliter bottle per 2 gallons of warm water (250 parts per million) for each treatment, for a total of 3 to 6 treatments, 14 days apart.

(3) *Limitations*. Continue treatment until no viable mites are found in skin scrapings at 2 successive treatments, or until 6 treatments have been applied. Do not use for treatment of localized demodicosis or scabies. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 18589, Apr. 30, 1982]

§ 524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

(a) *Sponsor*. To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000009; each gram contains 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B.

(2) To 000061 and 025463; each gram contains 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) *Conditions of use. Dogs and Cats—*
(1) *Amount.* Apply a thin film over the cornea 3 or 4 times daily.

(2) *Indications for use.* Treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to susceptible organisms.

(3) *Limitations.* Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000061; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone.

(2) To 025463; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

(b) *Conditions of use. Dogs and cats—*
(1) *Amount.* Apply a thin film over the cornea three or four times daily.

(2) *Indications for use.* For treating acute or chronic conjunctivitis caused by susceptible organisms.

(3) *Limitations.* All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. Federal law restricts

this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997]

§ 524.390 Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol.

(b) *Sponsors.* See Nos. 000856 and 025463 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*
(1) *Amount.* Apply every 3 hours around the clock for 48 hours, after which night instillations may be omitted.

(2) *Indications for use.* For treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 4897, Feb. 1, 2012]

§ 524.402 Chlorhexidine.

(a) *Specifications.* Each gram of ointment contains 10 milligrams chlorhexidine acetate.

(b) *Sponsors.* See Nos. 000856 and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs, cats, and horses—*(1) *Indications for use.* For use as a topical antiseptic ointment for surface wounds.

(2) *Limitations.* Do not use in horses intended for human consumption.

[72 FR 265, Jan. 4, 2007]

§ 524.450 Clotrimazole cream.

(a) *Specifications.* Each gram of cream contains 10 milligrams of clotrimazole.

(b) *Sponsor.* See 000859 in § 510.600(c).

(c) *Conditions of use—*(1) *Amount.* Apply ¼-inch ribbon of cream per square inch of lesion once daily for 2 to 4 weeks.

(2) *Indications of use.* For the treatment of fungal infections of dogs and cats caused by *Microsporium canis* and *Trichophyton mentagrophytes*.

(3) *Limitations.* Wash hands thoroughly after use to avoid spread of infection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 48128, July 18, 1980]